§ 558.195

or 50 percent coumaphos as in paragraphs (e)(2) and (e)(3) of this section.

- (2) No. 017800 for use of Type A medicated articles containing 1.12 or 11.2 percent coumaphos as in paragraph (e)(1) of this section.
- (c) Related tolerances. See 40 CFR 180.189.
- (d) Special considerations. Labeling shall bear the following caution statement: "The active ingredient coumaphos is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals." Also, see §500.25 of this chapter.
- (e) Conditions of use—(1) Beef and dairy cattle—(i) Amount. 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days. Should conditions warrant, repeat treatment at 30-day intervals.

(ii) Indications for use. Control of gastrointestinal roundworms (Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Trichostrongylus spp.).

- (iii) Limitations. Feed in the normal grain ration to which the animals are accustomed, but not in rations conmore 0.1 percent taining than coumaphos. Do not feed to animals less than 3 months old. Do not feed to sick animals or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks. Do not feed in conjunction with oral drenches or with feeds containing phenothiazine.
- (2) Laying chickens—(i) Amount. Coumaphos 27.2 grams per ton (0.003 percent).
- (ii) Indications for use. For control of capillary worm (Capillaria obsignata) and as an aid in control of common round worm (Ascaridia galli) and cecal worm (Heterakis gallinae).

(iii) Limitations. In Type C feed; administer continuously as the total feed ration for 14 days; when reinfection occurs, treatment may be repeated but not sooner than 3 weeks after the end of the previous treatment; do not feed to chickens within 10 days of vaccination or other conditions of stress; treatment of colored breeds of commercial layers should be avoided while in production since these breeds appear to

be more sensitive to coumaphos than white breeds; as sole medication; medications in general should be avoided while birds are approaching peak production; such interruption of normal feeding practices may upset the flock and lower egg production; diagnosis by competent personnel is essential; flock condition and production records should be carefully evaluated prior to treatment.

(3) Replacement pullets—(i) Amount. Coumaphos 36.3 grams per ton (0.004 percent).

(ii) Indications for use. For control of capillary worm (Capillaria obsignata) and as an aid in control of common roundworm (Ascaridia galli) and cecal worm (Heterakis gallinae).

(iii) Limitations. In Type C feed; administer before the onset of production; diagnosis by competent personnel is essential; administer continuously as total feed ration for from 10 to 14 days; do not feed to chickens under 8 weeks of age nor within 10 days of vaccination or other conditions of stress; if birds are maintained on contaminated litter or exposed to infected birds, a second 10 to 14 day treatment is recommended but not sooner than 3 weeks after the end of the previous treatment; as sole medication; if reinfection occurs after production begins, repeat treatment as recommended for laying flocks.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 1463, Jan. 7, 1977; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 61 FR 34729, July 3, 1996; 69 FR 70056, Dec. 2, 2004]

$\S 558.195$ Decoquinate.

- (a) Specifications. Type A medicated article containing 6 percent decoquinate.
- (b) Approvals. See No. 046573 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.170 of this chapter.
- (d) *Special considerations.* (1) Bentonite should not be used in decoquinate feeds.
- (2) Type A medicated articles may be used to manufacture dry or liquid Type B cattle (including veal calf), sheep, and goat feeds as in paragraphs (e)(2) and (e)(3) of this section.
- (3) Type C cattle feeds may be manufactured from decoquinate liquid Type

§ 558.195

Food and Drug Administration, HHS

B feeds having a pH between 5.0 to 6.5 and containing a suspending agent to maintain a viscosity of not less than 500 centipoises.

- (e) ${\it Conditions\ of\ use}.$ It is used as follows:
 - (1) Chickens.

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27.2		Broiler chickens: For prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima, and E. brunetti.	Do not feed to laying chickens.	046573
(ii) 27.2	Bacitracin methylene disalicylate 4 to 50.	Broiler chickens: As in paragraph (e)(1)(i) of this section; and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin methylene disalicylate as provided by No. 046573 in \$510.600(c) of this chapter.	046573
(iii) 27.2	Bacitracin zinc 10 to 50.	Broiler chickens: As in paragraph (e)(1)(ii) of this section	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin zinc as provided by No. 046573 in §510.600(c) of this chapter	046573
(iv) 27.2	Bacitracin zinc 12 to 50 plus roxarsone 11 to 45.	Broiler chickens: As in paragraph (e)(1)(ii) of this section	Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic Bacitracin zinc and roxarsone	046573
(v) 27.2	Bacitracin methylene disalicylate 50 and roxarsone 22.7 to 45.4.	Broiler chickens: As in paragraph (e)(1)(ii) of this section; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin; and for improved pigmentation	as provided by No. 046573 in §510.600(c) of this chapter Feed continuously as sole ra- tion; do not feed to laying chickens; withdraw 5 days before slaughter. Not for use in breeder chickens. Use as sole source of organic ar- senic. Poultry should have access to drinking water at all times. Drug overdosage or lack of drinking water may re- sult in leg weakness or paral- ysis	046573
			Bacitracin methylene disalicy- late and roxarsone as pro- vided by No. 046573 in §510.600(c) of this chapter	
(vi) 27.2	Chlortetracycline 100 to 200.	Chickens: As in paragraph (e)(1)(i) of this section; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; do not feed to chickens producing eggs for human consumption	046573
(vii) 27.2	Chlortetracycline 200 to 400.	Chickens: As in paragraph (e)(1)(i) of this section; and for control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline.	As in paragraph (e)(1)(vi) of this section	046573
(viii) 27.2	Lincomycin 2	Broiler chickens: As in paragraph (e)(1)(ii) of this section	Feed as sole ration; do not feed to laying chickens; linco-mycin provided by No. 000009 in § 510.600(c) of this chapter	000009 046573
(ix) 27.2	Roxarsone 45.4	Broiler chickens: As in paragraph (e)(1)(ii) of this section; and for improving pigmentation	Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic	046573

(2) Cattle.

§ 558.195

21 CFR Ch. I (4-1-05 Edition)

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8		Cattle (including ruminating and non- ruminating calves and veal calves): For prevention of coccidiosis caused by Eimeria bovis and E. zuernii.	Feed Type C feed or milk replacer to provide 22.7 milligrams (mg) per 100 pounds (lb) of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section.	046573
(ii) 12.9 to 90.8	Chlortetracycline 500 to 4,000	Calves, beef, and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by Escherichia coli; and for treatment of bacterial pneumonia caused by Pasteurella multocida organisms susceptible to chlortetracycline	Feed Type C feed to provide 22.7 mg decoquinate and 1 gram chlortetracycline per 100 lb body weight per day for not more than 5 days. When consumed, feed 22.7 mg decoquinate per 100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141–147. Zero withdrawal time when manufactured from AU-REOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.	046573
(iii) 12.9 to 90.8	Monensin 5 to 30	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; and for improved feed efficiency	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day and 50 to 360 mg of monensin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. Also see paragraph (d)(1) of this section and \$558.355(d)(8). Monensin as provided by No. 000986 in \$510.600(c) of this chapter	046573

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iv) 13.6 to 27.2	Chlortetracycline approximately 400 (varying with body weight and feed consumption to provide 10 mg/lb of body weight per day).	Calves, beef and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by <i>E. coli</i> ; and for treatment of bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline	Feed Type C feed to provide 22.7 mg decoquinate and 1 gram (g) chlorletracycline per 100 lb body weight (0.5 mg/ kg) per day for not more than 5 days. Type C feed may be prepared from Type B feed containing 535.8 to 5,440 g/ ton decoquinate and 6,700 to 80,000 g/ton chlorletracycline. When consumed, feed 22.7 mg decoquinate per 100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from chlorletracycline Type A medicated articles under NADA 141–147 and ANADA 200–359. Zero withdrawal time when manufactured from AUREOMYCIN (chlorletracycline) Type A medicated articles under NADA 141–185. Do not feed to calves to be processed for veal. Do not feed to animals producing milk for food. Chlorletracycline as provided by Nos. 046573 and 048164 in §510.600(c) of this chapter.	046573 048164
(v) 13.6 to 27.2	Monensin 5 to 30 plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for improved feed efficiency; and for reduction of incidence of liver abscesses caused by Fusobacterium necrophorum and Actinomyces (Corynebacterium) pyogenes	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day, 50 to 360 mg of monensin per head per day, and 60 to 90 mg of tylosin per head per day, and 60 to 90 mg of tylosin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Also see paragraph (d)(1) of this section and §558.355(d)(8). Monensin and tylosin as provided by No. 000986 in §510.600(c) of this chapter.	046573
(vi) 90.9 to 535.7		Cattle (including ruminating and non- ruminating calves and veal calves): As in paragraph (e)(2)(i) of this sec- tion	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lb of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section.	046573

21 CFR Ch. I (4-1-05 Edition)

§ 558.195

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(vii) 90.9 to 535.7	Chlortetracycline 4,000 to 20,000	Calves, beef, and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by Escherichia coli; and for treatment of bacterial pneumonia caused by Pasteurella multocida organisms susceptible to chlortetracycline	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg decoquinate and 1 gram chlortetracycline per 100 lb body weight per day for not more than 5 days. When consumed, feed 22.7 mg decoquinate per 100 lb body weight per day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141–147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.	046573

(3) Minor species.

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8		Young sheep: For the prevention of coccidiosis caused by Eimeria ovinoidalis, E. crandallis, E. parva, and E. bakuensis	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food	046573
		Young goats: For the prevention of coccidiosis caused by E. christenseni and E. ninakohlyakimovae	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for food.	
(ii) 90.9 to 535.7		Young sheep: As in item 1 of paragraph (e)(3)(i) of this section	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food	046573

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
		2. Young goats: As in item 2 of paragraph (e)(3)(i) of this section	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for food	

[67 FR 72370, Dec. 5, 2002; 68 FR 15372, Mar. 31, 2003; 69 FR 26499, May 13, 2004; 69 FR 52816, Aug. 30, 2004; 69 FR 62407, Oct. 26, 2004; 69 FR 67264, Nov. 17, 2004; 70 FR 2567, Jan. 14, 2005]

§558.198 Diclazuril.

(a) Specifications. Type A medicated article containing 0.2 percent diclazuril.

- (b) Approvals. See No. 000061 in \$510.600(c) of this chapter.
- (c) *Related tolerances*. See §556.185 of this chapter.
- (d) *Conditions of use.* (1) *Chickens.* For chickens it is used as follows:

Diclazuril grams/ ton	Combination grams/ ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 part per million (ppm)).		Broiler chickens: For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis (mivati), and E. maxima. Because diclazuril is effective against E. maxima later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with E. maxima.	Feed continuously. Not for use in hens producing eggs for human food	000061
(ii) 0.91 (1 ppm)	Bacitracin methylene disalicylate 4 to 50.	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency	As in item (i) of this table. Baci- tracin methylene disalicylate provided by 046573	000061
(iii) 0.91 (1 ppm).	Bacitracin methylene disalicylate 50 plus roxarsone 22.7 to 45.4.	Broiler chickens: As in item (i) of this table; as an aid in the prevention of necrotic entertits caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bactracin; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration throughout growing period. Use as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Not for use in hens producing eggs for human consumption. Withdraw 5 days before slaughter. Bacitracin methylene disalicylate and roxarsone provided by No. 046573 in §510.600(c) of this chapter	000061